

AMENDMENTS TO THE CLAIMS

Please amend the claims as follows:

40. – 43. (Canceled)

44. (Currently Amended) A ready-for-use sterile, stable, pharmaceutical formulation, in a closed system, comprising an injectable aqueous solution of crystals free from alkaline residues from active principle 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one as its free acid form, produced by the process ~~of claim 1~~ described in any one of claims 47 to 50, diluted in glucose 5% solution or sodium chloride 0.9% solution, with pH ranging from 3.0 to 6.9, and being packed in a flexible bag manufactured with a tri-laminated material composed by three distinct layers, being an external layer of polyester, an intermediate layer of polyethylene and the inner layer of propylene copolymer.

45. (Previously Presented) The Pharmaceutical formulation according to claim 44, in which the solution is a sodium chloride 0.9% solution, and the pH is within the range of 4.5 to 6.9.

46. (Previously Presented) The Pharmaceutical formulation according to claim 44, in which the solution is a glucose 5% solution, and the pH is within the range of 3.2 to 6.5.

47. (New) Process of making crystals of 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one, free from alkaline residues to manufacture the pharmaceutical formulation described on claims 44 to 46, comprising:

a) Suspending in a glass reactor coupled with a condenser apparatus 80 to 110g of the 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one (free base) in 0.9 to 1.1l of demineralized water under stirring and room temperature until complete homogenization and obtaining of aqueous 9-((1,3-DIHYDROXYPROPAN-2-YLOXY)METHYL)-2-AMINO-1H-PURIN-6-(9H)-ONE (free base);

b) Elevating the pH to a range between 10.5 and 12.5 by adding an 13.5 to 16.5g of inorganic base under stirring until the total dissolution of all solids;

- c) Elevating the temperature of the resulting solution 1(b) to a range between 75° and 90°C;
- d) Adding an inorganic or organic acid, thus adjusting the pH into a range from 4.5 to 5.5;
- e) Cooling the solution to a temperature ranging from 5° to 7°C and keeping the resulting crystals of 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1h-purin- 6-(9h)-one under stirring for 25 to 40 minutes;
- f) Filtering the resulting crystals from 1(e) and washing the crystals with an organic solvent selected from the group comprising acetone, ethanol, methanol and isopropanol in a ratio of 1/10 of the water volume used in the beginning of the process;
- g) Heating and stirring until intensely refluxing, in a glass lined reactor with a reflux condenser, the resulting crystals from 1(f) in an organic solvent selected from the group comprising of methanol, ethanol, propanol, isopropanol and butanol, for a period of time ranging from 3 to 4 hours, wherein the organic solvent is added in a ratio of 4 to 6 parts in relation to the solid mass of 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2- amino-1h-purin-6-(9h)-one;
- h) Cooling the resulting suspension from 1(g) to a temperature ranging from 20° and 30°C, filtering the crystals and drying them under vacuum at temperature ranging from 60° and 80°C for 3 to 5 hours, thus obtaining 90.4g to 100.4g of crystals of 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one that are free from alkaline residues.

48. (New) The Process according to claim 47, in which the inorganic base used in 1(b) is selected from the group consisting of potassium hydroxide, lithium hydroxide and sodium hydroxide.

49. (New) Process according to claim 48, in which the inorganic base is sodium hydroxide.

50. (New) Process according to claim 47, in which the organic solvent used in steps 1(f) and 1(g) is isopropanol.